



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JAN 10 2017

The Smithworks Company
C/O Ms. Patricia A. Milbank
Regulatory Consultant
2615 102nd Avenue NE
Bellevue, Washington 98004

Re: K060851

Trade/Device Name: The Smithworks Company IV Fluid Warmer, Product Line:
Soft Sack iv Fluid Warmer, FloorMount iv Fluid Warmer,
Pak 2 iv Fluid Warmer and Thermal Sack Pressure Infuser
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LGZ
Dated: November 28, 2006
Received: December 1, 2006

Dear Ms. Milbank:

This letter corrects our substantially equivalent letter of December 22, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809]), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1 Indication(s) for Use Statement

510(k) Number: K060851

Device Name: The Soft Sack iv fluid warmer

Indications for Use:

The Soft Sack iv fluid warmer is indicated for the warming or thermal maintenance of intravenous fluids prior to administration. This device is intended for use with crystalloid fluids only, such as normal saline and ringers lactate. This device is intended to be used by healthcare professionals in hospital, clinical and field environments.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


David A. Williams, M.D.
Chief of Anesthesiology, General Hospital
FDA, Center for Device and Research
Non Control, Dental Devices

K060851

1 Indication(s) for Use Statement

510(k) Number: K060851

Device Name: The FloorMount iv fluid warmer

Indications for Use:

The FloorMount iv fluid warmer is indicated for the warming or thermal maintenance of intravenous fluids prior to administration. This device is intended for use with crystalloid fluids only, such as normal saline and ringers lactate. This device is intended to be used by healthcare professionals in hospital, clinical and field environments.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shirley H. Murphy, MD for Chiu Lin Ph D

General Counsel

for the ODE

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1 Indication(s) for Use Statement

510(k) Number: K060851

Device Name: The PAK2 iv fluid warmer

Indications for Use:

The PAK2 iv fluid warmer is indicated for the warming or thermal maintenance of intravenous fluids prior to administration. This device is intended for use with crystalloid fluids only, such as normal saline and ringers lactate. This device is intended to be used by healthcare professionals in hospital, clinical and field environments.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shirley H. Murphy, R. for Chiu Lin, Ph.D.

Biotechnology, General Hospital,
for General Dental Devices

K060851

1 Indication(s) for Use Statement

510(k) Number: K060851

Device Name: Thermal Sack Pressure Infuser

Indications for Use:

The Thermal Sack Pressure Infuser is a thermal maintenance device. It is intended for use as an accessory for use with iv fluid warmer devices to enhance the ability to deliver thermal normal iv fluids in the field, by insulating the bag and tubing. This device is intended for use with crystalloid fluids only, such as normal saline and ringers lactate. This device is intended to be used by healthcare professionals in clinical and field environments. This device has not been tested for pediatric use.

Prescription Use ☒
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
 (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shirley H. Murphy, MD for Chen S. Lu, PhD
Director, General Hospital
and Center for Medical Devices
K060851

1 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted as part of the PreMarket Notification in accordance with the requirements of 21 CFR Part 807, Subpart E and Section 807.92.

1. Identification of Submitter:

Submitter: The Smithworks Company
839 11th Street
Clarkston, WA 99403
Phone: 800-576-3454
Fax: 509-758-5942

Contact: Patricia A. Milbank, JD
Title: Regulatory Consultant
2615 102nd Ave NE
Bellevue, WA 98004
Phone: 425-894-9733
Fax: 425-822-3648
Date Prepared: November 29, 2006

2. Identification of Products bundled within this 510(k) submission:

Trade Names: Soft Sack iv fluid warmer
FloorMount iv fluid warmer
Pak 2 iv fluid warmer
Thermal Sack Pressure Infuser

Regulatory Number: unclassified
Common Name: Warmer, Thermal, Infusion Fluid
Regulatory Class: Class II
Product Code: LGZ

Manufacturer: The Smithworks Company
839 11th Street
Clarkston, WA 99403

3. Indications for Use Statements

Soft Sack iv Fluid Warmer

The Soft Sack iv fluid warmer is indicated for the warming or thermal maintenance of intravenous fluids prior to administration. This device is intended for use with crystalloid fluids only, such as normal saline and ringers lactate. This device is intended to be used by healthcare professionals in hospital, clinical and field environments.

FloorMount iv Fluid Warmer

The FloorMount iv fluid warmer is indicated for the warming or thermal maintenance of intravenous fluids prior to administration. This device is intended for use with crystalloid fluids only, such as normal saline and ringers lactate. This device is intended to be used by healthcare professionals in hospital, clinical and field environments.

Pak 2 iv Fluid Warmer

The Pak 2 iv fluid warmer is indicated for the warming or thermal maintenance of intravenous fluids prior to administration. This device is intended for use with crystalloid fluids only, such as normal saline and ringers lactate. This device is intended to be used by healthcare professionals in hospital, clinical and field environments.

Thermal Sack Pressure Infuser

The Thermal Sack Pressure Infuser is a thermal maintenance device. It is intended for use as an accessory for use with iv fluid warmer devices to enhance the ability to deliver thermal normal iv fluids in the field, by insulating the bag and tubing. This device is intended for use with crystalloid fluids only, such as normal saline and ringers lactate. This device is intended to be used by healthcare professionals in clinical and field environments. This device has not been tested for pediatric use.

4. Device Descriptions:

Each of the iv fluid warmer devices (Soft Pack, FloorMount and Pak 2) employs a heating plate or heating blanket to warm or maintain the temperature of iv fluids such as normal saline and ringers lactate. These devices use a standard temperature control method and operate reliably in the range of 36-38 degrees C. The Smithworks products are designed to use a 40 watt, 12 VDC with an optional 120 VAC adaptor, for enhanced safety and portability when used in the field.

The Thermal Sack Pressure Infuser is an accessory to the Smithworks iv fluid warmer components. This device is wrapped around the iv fluid bag and is used to apply even pressure to the iv fluid bag when it cannot be maintained in the standard hanging state, which applies normal gravity pressure. This

device should only be used in conditions that require emergency personnel to move victims in conditions that prevent a normal gravity based suspension of the iv fluid bag, and when the rescue mission is conducted by a limited number of emergency medical personnel.

Features of the Soft Sack IV Fluid Warmer:

- 40 watt, 12 volt operation for personal safety and gentle, even heating of solutions
- Operates on standard 12 volt DC automotive current
- Optional 120 VAC with 12 VDC adaptor available
- Maintains 3 liters of IV fluid to a temperature of 99-101 degrees Fahrenheit (36-38 degrees C)
- Rugged anodized aluminum case to protect the electronics
- Over-therm fuse protects silicone heater
- Fused circuit board controller for accurate thermal regulation and safety
- Exterior bag is built of rugged Cordura fabric for durability
- Reflective materials meet highway safety requirements
- Lined with Thinsulate insulation and Mylar heat reflective material

Features of the FloorMount IV Fluid Warmer:

- 40 watt, 12 volt operation for personal safety and gentle, even heating of solutions
- Operates on standard 12 volt DC automotive current
- Optional 120 VAC with 12 VDC adaptor available
- Maintains 4 liters of IV fluid to a temperature of 99-101 degrees Fahrenheit (36-38 degrees C)
- Rugged anodized aluminum case to protect the electronics
- Over-therm fuse protects silicone heater
- Fused circuit board controller for accurate thermal regulation and safety

Features of the Pak 2 IV Fluid Warmer:

- 40 watt, 12 volt operation for personal safety and gentle, even heating of solutions
- Operates on standard 12 volt DC automotive current
- Optional 120 VAC with 12 VDC adaptor available
- Maintains 4 liters of IV fluid to a temperature of 99-101 degrees Fahrenheit (36-38 degrees C)
- Rugged anodized aluminum case to protect the electronics
- Over-therm fuse protects silicone heater
- Fused circuit board controller for accurate thermal regulation and safety

- Provides an alternative for non-transport ALS emergency vehicles
- Designed for transport in a Plano 747 box

Features of the Thermal Sack Pressure Infuser:

- A thermal maintenance device, designed for use with the Soft Sack IV Fluid Warmer, the FloorMount IV Fluid Warmer or the Pak 2 IV Fluid Warmer.
- Designed for use in wilderness rescue operations or rescue operations where ambient temperature will affect the temperature of warmed fluids.

5. Comparison with Legally Marketed Devices

Several iv fluid warmers have been cleared by FDA for use in hospital, clinical and field environments. These systems have been cleared under two product codes: iv fluid warmers have been assigned the product code LGZ and remain "unclassified," whereas products intended for use as blood/fluid warmers have been classified as BSB under 21 CFR 864.9205 Both categories of these products have been cleared as Class II medical devices.

The predicate devices cited in this submission have been cleared under the 510(k) PreMarket Notification process. The predicate devices are as follows:

510(k) No.	Trade Name	Manufacturer	Product Code	Regulation Number
K973741	Bair Hugger Blood/Fluid Warmer	Augustine Medical, Inc.	BSB	864.9205
K984640	Thermal Angel 200 Blood/Fluid Warmer	Estill Medical Technologies, Inc.	BSB	864.9205
K002409	MaxOne IV Fluid/Blood Warmer	Automatic Medical Technologies, Inc.	LGZ, subsequent code BSB	Unclassified and 864.9205
K921395	Hot Sack and Optional Insulated IV Sleeve	C.F. Electronics	LGZ	Unclassified
K012276 and K041839	Listed as "Heat Stack Devices": filed as "Temp 3" and "8None"	Medical Solutions, Inc.	LGZ	Unclassified

Similarities:

The Smithworks iv fluid warmer product line is designed to provide external warming of iv bags containing normal crystalloid iv solutions. In this application, the Smithworks iv fluid warmers incorporate features that are substantially equivalent to the features provided by the legally marketed iv fluid warmer devices cited above. All of the iv fluid warmers are designed for use in the hospital, clinical or field environment.

Each device employs a heating element to warm iv fluids. All of the devices use a standard temperature control method and have an established range of operation for the temperature control (typically 33-41 degrees C). The Smithworks products are individually tested to operate reliably in the range of 36-38 degrees C.

As with the Hot Sack device, the Smithworks product packaging and components have been optimized for mobile use, such as rescue and emergency operations. Also, the power source for the Smithworks iv fluid warmer devices is provided by a 12V battery or 100-120 VAC. The Smithworks products are designed to use a 40 watt, 12 VDC with an optional 120 VAC adaptor, for enhanced safety and portability when used in the field.

The proposed indications for use statement for the Smithworks Company Soft Pack, FloorMount and PAK2 iv fluid warmer products is substantially equivalent to the approved indications for use statements provided in the labeling for the cited predicate devices.

Finally, Smithworks provides an optional accessory for use with its iv fluid warmer devices, the Thermal Sack Pressure Infuser, an accessory that is equivalent to the Hot Sack Optional Insulated IV Sleeve. These devices are both designed to provide thermal maintenance of previously warmed iv fluids and to help maintain a steady flow rate of iv fluids during rescue operations in hostile rescue environments, such as extreme temperature/wind chill conditions.

Differences:

The cited predicate devices that are classified under product code BSB (see Table, above) also provide "in-line" warming of blood and/or iv fluids. The Smithworks products do not provide this functionality. Smithworks iv fluid warmer products are only intended for use for the warming of iv fluid bags containing crystalloid fluids, such as Ringer's lactate or normal saline, using conduction from an external electronic component.

6. Conclusions

The Smithworks Company iv fluid warmer products, the Soft Sack, the FloorMount and the Pak2, are substantially equivalent to the identified legally marketed devices intended for use in warming iv bags containing crystalloid fluids, such as Ringer's lactate or normal saline, using conduction from an external electronic component.

The Thermal Sack Pressure Infuser is equivalent to a previously cleared device marketed as an accessory for use with iv fluid warmers to provide

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thermal maintenance of previously warmed iv bags and steady flow rates during rescue operations in hostile environments.

The potential hazards have been studied and controlled as part of the product development process, including risk analysis, test and design considerations, and planned verification and validation testing processes. The Smithworks Company iv fluid warmer products operate in hospital, clinical and field environments in a manner comparable to the predicate devices.